ode: 4150-28

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS-0990-0278]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795-7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-0278-60D and project title for reference, to Sherrette A. Funn, email: Sherrette.Funn@hhs.gov, or call (202) 795-7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Federalwide Assurance (FWA) Form

Type of Collection: Extension

OMB No. 0990-0278

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research

Protections (OHRP), is requesting a three-year extension of the OMB No. 0990-0278,

Federalwide Assurance (FWA) Form, with no changes in the collected information. The purpose

of the FWA form is to provide a simplified procedure for institutions engaged in research

conducted or supported by the Department of Health and Human Services (HHS) to satisfy the

assurance requirements of (1) Section 491(a) of the Public Health Service Act (the PHS Act) (42

U.S.C. 289); and (2) HHS regulations for the protection of human subjects at 45 CFR 46.103.

Likely Respondents: Institutions engaged in HHS-conducted or –supported research involving human subjects.

Annualized Burden Hour Table

Form name	Number of	Number of	Hours per	Response
	Respondents	Responses per	Response	Burden Hours
	_	Respondent	_	
Federalwide	14,000	2.0	30/60	14,000
Assurance (FWA)				
Total				14,000

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer,

Office of the Secretary.

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